Restriction/Election

Restriction to one of the following inventions has been required under 35 USC 121:

I. Claims 1-8, 15, and 16, drawn to a method of extending survival and/or delaying disease progression by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-5643 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby disease progression is delayed and/or survival is extended, classified in class 424, subclass 178.1.

II. Claims 9-13, drawn to an isolated monoclonal antibody or antigen binding fragments thereof encoded by the clone deposited with the ATCC as PTA-5643, classified in class 530, subclass 388.1.

The Examiner has also required the following Species Elections:

Species Elections for Group I

A. Claim 1 is generic to the following disclosed patentably distinct species of administered antibodies:

1) antibody alone

2) conjugated to cytotoxic moiety

B. Claim 1 is generic to the following disclosed patentably distinct species of antibodies:

1) antibody activates complement

2) antibody mediates antibody dependent cellular cytotoxicity

C. Claim 1 is generic to the following disclosed patentably distinct species "tumor":

1) breast tumor

2) ovarian tumor

Species Elections for Group II

A. Claim 9 is generic to the following disclosed patentably distinct species "conjugates":

1) cytotoxic moieties

2) enzymes

3) radioactive compounds

4) hematogenous cells

REMARKS

Applicants herein elect, without traverse, Group I (claims 1-8, 15 and 16) for prosecution on the merits. Additionally, Applicants herein elect, with traverse, species A1 (antibody alone), species B2 (antibody mediates antibody dependent cellular cytotoxicity) and species C1 (breast tumor).

Applicants are not required to make any election of species with regard to Group II since Applicants elected Group I for prosecution on the merits.

Claim 14 was cancelled in the Preliminary Amendment filed in July 26, 2006. Claims 2-4, 9-13 and 16 are withdrawn from consideration. It is understood that claims 2-4, 9-13 and 16, drawn to the non-elected inventions and species, will remain pending, albeit withdrawn from consideration on the merits at this time. Applicants retain the right to present the non-elected claims 2-4, 9-13 and 16 in a divisional application.

No new matter has been added by the amendment to the specification made herein. The "Reference to Related Applications" section has been amended to update the status of the related applications.

Election of Group

The Examiner asserts that the Inventions of Group II and Group I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP 806.05(h).

The Examiner asserts that, in the instant case, the monoclonal antibody can be used in immunoaffinity chromatography.

Furthermore, the Examiner asserts that searching all of the claims (i.e., both Groups) would invoke a burdensome search because the inventions have been classified separately. Thus, each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. This would necessitate different searches in the patent and/or non-patent literature and the consideration of different patentability issues.

The Examiner concludes that because these invention are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Applicants herein elect, without traverse, Group I (claims 1-8, 15 and 16) for prosecution on the merits.

Traversal of the Election of Species

The Examiner asserts that the species designated are independent or distinct because they comprise structurally distinct molecules and have different modes of operation and different effects. Further, each species would require different searches and the consideration of different patentability issues.

The Examiner first requires an election of the antibody alone (non-conjugated) or an antibody conjugated to a cytotoxic moiety.

Applicants respectfully submit that the non-conjugated and conjugated antibodies are not independent inventions since conjugation is a further limitation on the antibody. Furthermore, conjugated antibodies comprise the same antibody as the non-conjugated antibodies (shared structure) which works by binding an antigenic moiety (shared mode of operation) to treat a cancerous disease (shared effects). A search for a non-conjugated antibody and the conjugated antibody clearly overlaps.

Thus, Applicants respectfully submit that this election of species (non-conjugated and conjugated) is improper.

The Examiner next requires an election of the type of cytotoxicity mediated by the antibody (antibody activates complement or antibody mediates antibody dependent cellular cytotoxicity).

Both types of cytotoxicity mediated by the described antibody are not independent inventions because each type places a further limitation on the antibody by defining how the cytoxicity of the antibody is acheived. Both types have the same effect, i.e. cytotoxicity. A search of the prior art should center on the specific monoclonal antibody. For example, one of skill in the art would not attempt to search each of the types of cytotoxicity mediated without connecting the search to the antibody since a search of both types alone would result with thousands of hits related to many different antibodies.

Accordingly, the search for types of cytotoxicity is considered overlapping and thus, the election of species is improper.

The Examiner also requires an election of species of tumor (breast or ovarian).

Each type of tumor tissue is not an independent or distinct invention. The tumor tissue is not a step of the described methods. Cells obtained from both of these tumor tissues were used with the same claimed methods. These methods operate the same way in both of the tissues, i.e. the antibody binds the same antigenic moiety in both of the tissues. The instant inventors found that human tumor cells obtained from breast and ovarian tissues expressed an antigenic moiety which bound the described monoclonal antibody encoded by the clone deposited with the ATCC as PTA-5643 and thus were able to be treated successfully with the described monoclonal antibody. A search of the prior art regarding tumor tissues should center on the specific monoclonal antibody. For example, when one of skill in the art searches the antibody one would expect to retrieve information about the antibody including any tissues with which the antibody is involved.

Accordingly, this search for types of tumor tissue is considered overlapping and thus, the election of species is improper.

Accordingly, based upon all of the above arguments, Applicants respectfully request that the Examiner reconsider the requirement for election of species.

CONCLUSION

Now that Applicants have fully responded to the Office Action mailed on August 7, 2006, an examination on the merits is respectfully requested.

Respectfully submitted,

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